

WEST

Help

Logout

Interrupt

Main Menu

Search Form

Posting Counts

Show S Numbers

Edit S Numbers

Preferences

Cases

Search Results -

Terms	Documents
L8 hsa	7

Database:

US Patents Full-Text Database
 US Pre-Grant Publication Full-Text Database
 JPO Abstracts Database
 EPO Abstracts Database
 Derwent World Patents Index

IBM Technical Disclosure Bulletins

Search:

L9

Refine Search

Recall Text

Clear

Search History
DATE: Monday, September 16, 2002 [Printable Copy](#) [Create Case](#)
Set Name Query
 side by side

Hit Count Set Name
 result set

DB=USPT,PGPB,JPAB,EPAB,DWPI; PLUR=YES; OP=AND

<u>L9</u>	L8 hsa	7	<u>L9</u>
<u>L8</u>	L7 buffer	51	<u>L8</u>
<u>L7</u>	L6 lactose	59	<u>L7</u>
<u>L6</u>	L4 powder pulmonary	73	<u>L6</u>
<u>L5</u>	L4 spray-dried powder	11	<u>L5</u>
<u>L4</u>	"follicle stimulating hormone" aerosol	235	<u>L4</u>
<u>L3</u>	"folicule stimulating hormone" aerosol	0	<u>L3</u>
<u>L2</u>	FSH aerosol "amino acid" mmd micron powder	11	<u>L2</u>
<u>L1</u>	aerosol spray-dried powder FSH pulmonary	12	<u>L1</u>

END OF SEARCH HISTORY

WEST



Generate Collection

Print

L1: Entry 8 of 12

File: USPT

Apr 16, 2002

US-PAT-NO: 6372258

DOCUMENT-IDENTIFIER: US 6372258 B1

TITLE: Methods of spray-drying a drug and a hydrophobic amino acid

DATE-ISSUED: April 16, 2002

INVENTOR-INFORMATION:

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US-CL-CURRENT: 424/489; 424/45, 424/46, 424/85.6, 514/2

CLAIMS:

The subject matter claimed is:

1. A method for spray-drying a pharmaceutical-based dry powder, said method comprising:

providing a mixture of a drug and a hydrophobic amino acid in a suitable solvent, and

spray-drying the mixture under conditions effective to provide a respirable dry powder comprising particles, wherein at least about 95% of the mass of the powder has a particle size below 10 .mu.m.

2. The method of claim 1, wherein said solvent is water.

3. The method of claim 1, wherein said hydrophobic amino acid is selected from the group consisting of tryptophan, tyrosine, leucine, and phenylalanine.

4. The method of claim 1, wherein a pharmaceutically-acceptable carrier is also provided in said providing step.

5. The method of claim 4, wherein the carrier comprises a carbohydrate bulking agent.

6. The method of claim 4, wherein the carrier comprises human serum albumin.

7. The method of claim 5, wherein the bulking agent is mannitol.

8. The method of claim 1, wherein about 80% of the mass of the spray-dried powder has a particle size of less than 5 .mu.m.

9. The method of claim 1, wherein the particles have an aerosol particle size distribution of about 1.0-5.0 .mu.m MMAD.

10. The method of claim 1, wherein the hydrophobic amino acid is leucine.

11. The method of claim 1, wherein the spray-dried powder is further characterized by a delivered dose of greater than about 30%.

12. A method for spray-drying a pharmaceutical-based dry powder, said method comprising:

providing a mixture of a drug and a hydrophobic amino acid in a suitable solvent, and

spray-drying the mixture under conditions effective to provide a respirable dry powder comprising particles having an aerosol particle size distribution of about 1.0-5.0 μm MMAD.